Senator Ted W. Lieu
28th Senate District

Senate Bill 600
Drug, Quality and Security Act Conformity
Fact Sheet

Issue:

In 2013, Congress passed and President Obama signed H.R. 3034, the Drug, Quality and Security Act (DQSA). Among other provisions, the bill created a national set of standards to track pharmaceuticals through the distribution chain, aimed at curbing illegal importation and patient harm caused by counterfeit drugs and devices. The new law requires the Food and Drug Administration (FDA) to implement an electronic system to trace pharmaceuticals throughout the supply chain at the unit level and, as a result, preempts California's E-pedigree law established in 2005.

Background:

Drugs and devices obtained from foreign sources, which may be sold at lower prices in foreign countries due to artificial price controls in these other countries, as well as a lack of compliance with FDA regulations by some foreign and unlicensed importers, patients may be treated with drugs and devices that are represented as FDA-approved but are often of unknown origin and quality which can result in significant harm to these patients. When a drug is illegally imported, there is no guarantee as to the active ingredients in the drug or the potency of the drug. Imported drugs may contain too little active ingredient, in which case therapeutic effects will be minimized. Alternatively, these products may contain too much active ingredient, which can result in harm to consumers and negative interactions with other medications.

Manufacturing, storage, packaging and transportation of imported drugs are not regulated by the FDA. This can lead to degradation of the product and harm to consumers. Some imported medicines – even those that bear the name of a U.S.-approved product – may, in fact, be counterfeit versions that are unsafe or even completely ineffective. Some imported medicines and their ingredients, although legal in foreign countries, may not have been evaluated for safety and effectiveness in the United States. These products may be addictive or may contain other dangerous substances. Imported drugs may be labeled in languages that American consumers do not understand and may make medical claims or suggest specific uses that have not been adequately evaluated for safety and effectiveness. Additionally, imported drugs may lack information about side effects caused by the medicine.

Proposal:

This bill conforms to DQSA by repealing California's E-pedigree law, strengthening definitions for misbranded drugs and devices under California's Sherman, Food, Drug and Cosmetics Act and ensuring appropriate penalties for purchasing a foreign dangerous drug or medical device, illegitimate product, or suspect product.

Support:

Healthcare Distribution Management Association
Los Angeles County District Attorney's Office

Neutral:

California Retailers Association
Generic Pharmaceuticals Association
National Association of Chain Drug Retailers
Pharmaceutical Research and Manufacturers of America (PhRMA)

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